

PATENT COOPERATION TREATY

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INTERNATIONAL PRELIMINARY EXAMINATION REPORT (PCT Article 36 and Rule 70)

Applicant's or agent's file reference P47001A	FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/PEA/416)	
International application No. PCT/B 03/01392	International filing date (day/month/year) 10.03.2003	Priority date (day/month/year) 08.03.2002
International Patent Classification (IPC) or both national classification and IPC A61M16/00		
Applicant KAERY S.A. et al.		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 4 sheets, including this cover sheet.
 - ☒ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of 8 sheets.

3. This report contains indications relating to the following items:
 - I ☒ Basis of the opinion
 - II ☐ Priority
 - III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
 - IV ☐ Lack of unity of invention
 - V ☒ Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
 - VI ☐ Certain documents cited
 - VII ☐ Certain defects in the international application
 - VIII ☐ Certain observations on the international application

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Name and mailing address of the international preliminary examining authority:  European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized Officer Storer, J Telephone No. +49 89 2399-7247



INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/IB 03/01392

I. Basis of the report

1. With regard to the **elements** of the international application (*Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17)*):

Description, Pages

1, 2, 4-24 as originally filed
3, 3a filed with telefax on 25.05.2004

Claims, Numbers

1-23 filed with telefax on 25.05.2004

Drawings, Sheets

1/13-13/13 as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
☐ the language of publication of the international application (under Rule 48.3(b)).
☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
☐ filed together with the international application in computer readable form.
☐ furnished subsequently to this Authority in written form.
☐ furnished subsequently to this Authority in computer readable form.
☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

- ☐ the description, pages:
☐ the claims, Nos.:
☐ the drawings, sheets:

**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT**

International application No. PCT/IB 03/01392

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)).

(Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes: Claims	1-23
	No: Claims	
Inventive step (IS)	Yes: Claims	1-23
	No: Claims	
Industrial applicability (IA)	Yes: Claims	1-23
	No: Claims	

2. Citations and explanations

see separate sheet

Re Item V

Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. The invention concerns an apparatus to assist a patient respiration by delivering air through a mask, comprising an air blower wherein the impeller is rotated by an electro motor, for which the closest prior art is US-A1-20020000228.
 - 1.1 The problem addressed by the invention is how to provide an apparatus able to deliver air to a patient at a controlled pressure in such a way that the pressure can be modulated within a breath according to the breath pattern.
 - 1.2 The problem is solved by providing a driving unit which comprises means to sense the back electro motor force generated by the electro motor for changing the sectors' polarity configuration when the back electro motor force reaches the zero value.
 - 1.3 The provision of a driving unit with means to sense the back electro motor force generated by the electro motor for changing the sectors' polarity configuration when the back electro motor force reaches the zero value is not suggested by the available prior art. Therefore, the subject-matter of claim 1 is novel and is considered to be inventive. The industrial applicability of the invention is self-evident, therefore claim 1 satisfies the requirements of Article 33(2)-(4) PCT. Since claims 2-23 are dependent on claim 1, these likewise satisfy the requirements of the PCT with respect to novelty, inventive step and industrial applicability.
2. The description should have been brought into line with the claims to meet the requirements of Rule 5.1(a)(iii) PCT.

requiring the use of a 22 millimeters diameter tube as the pressure drop within such a tube is negligible but the use of a smaller tube will not guarantee the pressure regulation within acceptable bounds.

5 In the case of two levels of pressure apparatus, as changing the blower speed within a breath is impossible to achieve due to the high inertia, the highest level is delivered by the blower and the lowest is managed by using pneumatic valves, pressure dividers or alternative methods.

10 The size of the impeller, the sensor positioning and attachments and the number of wires required increase the size of the blower and thus of the apparatus. Furthermore the precise positioning of the sensors complicates the assembling of the motor implying an increase of the cost.

15 In US 2002/0000228, the inventors have used a way to obtain fast accelerations and decelerations which does not relies on the positioning of the rotor. US 2002/0000228 discloses a blower for an air assistance apparatus. The blower operates with an electric motor. The polarity of the stator's
20 sectors are changed by a driving unit to achieve fast accelerations and decelerations in one patient's breath step. This result is obtained by using a compressor wheel with a very low mass and by holding the wheel without contact in the radial compressor. This system requires a lot of precision
25 when assembling the motor to obtain the magnetic fields that will hold the wheel without contact in the compressor. The rotor position can not be determined.

Document US 5977737 relates to a way to enhance the accuracy of the motor functions. The improvement of the
30 accuracy is carried out by predicting the motor current. There are no means for sensing the motor current. The prediction of the motor current is made by using different parameters such as motor inductance, motor and driver resistance and the back-electro motor force (back-EMF) value. The motor's position may
35 also be included as one of the parameters. Using these parameters the current is calculated. This allows the

3A

determination of the pulse widths to be applied to various inputs to the driver circuit. The back-EMF is not used to determine the rotor's position and to change the sector's polarity in respect of this position. US 5977737 does not disclose a way to determine the rotor's position. The aspect disclosed by US 5977737 is a more accurate delivery of current and not a way for increasing the electro motor's efficiency. This document thus does not provide any indication to obtain fast accelerations and decelerations within a patient's breath.

Summary of the invention

The invention object is to provide an apparatus able to deliver air to a patient at a controlled pressure in such a way that the pressure could be modulated within a breath according to the breath pattern and according to events detected from the patient .

Another object is to provide an apparatus enabling the use of smaller diameter tubes than the standard 22mm.

Another object of the invention is to provide an apparatus with a lower size, being more power efficient and to improve comfort, to be as quiet as possible.

A further object is to provide an apparatus easier and cheaper to assemble.

The subject of the invention is an apparatus able to deliver air to a patient at a controlled pressure in such a way that the pressure could be modulated within a breath according to the breath pattern and according to events detected from the patient .

This is obtained by a very efficient centrifugal blower which is able to rotate at high speed (up to 50000 round per minute) and to decelerate and accelerate very quickly (± 10 hPa

CLAIMS

1. An apparatus (1) to assist a patient respiration by delivering air to this patient through a mask, comprising an air blower (33) wherein the impeller (5) is rotated by an electro motor comprising a rotor (3) and a stator (8), said stator having at least three sectors (8a, 8b and 8c), the rotation of the rotor being enabled by changes of the polarity of the sectors, each sectors' polarity configuration constituting one step of the rotor's rotation, said apparatus comprising a driving unit (36) controlling changes of the sectors polarity configuration such that the electro motor enables the blower to achieve fast accelerations and decelerations within one patient's breath step, said breath step consisting of one inspiration and one expiration ; characterized in that said driving unit comprises means to sense the back electro motor force generated by the electro motor for changing the sectors polarity configuration when the back electro motor force reaches the zero value.

2. The apparatus (1) according to claim 1, wherein said stator (8) has at least three sectors (8a, 8b and 8c), each of said sectors being connected to one switch (HA, HB, or HC) connected to the positive plot of the power supply and each of said sectors being connected to one switch (LA, LB or LC) connected to the negative plot of the power supply, in order that one of the rotor's rotation step is obtained when said driving unit (36) applies the tension to the stator by connecting the first sector (8a) to said positive plot, connecting the second sector (8b) to the negative plot and setting the third sector (8c) not connected to a power supply plot, thus enabling to measure the back electro motor force of the motor between the third sector and the negative plot, said driving unit changing the sectors polarity configuration when the back electro motor force reaches the zero value.

3. The apparatus (1) according to claim 2, wherein said tension applied is a Pulse Width Modulation, the driving unit connecting one of said stator sectors (8a, 8b or 8c) to the

positive plot during a first duration of time and then, and then, during a second period, disconnecting the same sector from the positive plot and connecting it to the negative plot, so that in case of deceleration of the motor the generated
5 current is sent to the negative plot, thus providing a fast deceleration of the impeller (5).

4. The apparatus (1) according to claim 2 or 3, wherein said stator (8) is a three sectors stator and said rotor is a dipole magnet, said stator thus having six sectors polarity
10 configuration so that the rotor performs one 360° rotation in six rotation steps.

5. The apparatus according to any one of claims the previous claims, wherein said stator (8) is a toroidal stator and wherein each of said sectors (8a, 8b or 8c) are coils
15 connected with only one wire.

6. The apparatus according to any one of the previous claims, wherein when the blower (33) is functioning and no back electro motor force is measured, said driving unit (36) fixes the tension applied and changes the sectors (8a, 8b and
20 8c) polarity configuration after a given time, said driving unit decreasing this given time every step until a back electro motor is detected and then applying the required tension and changing the sectors polarity configuration according to the back electro motor value.

7. The apparatus according to any one of the previous claims, further comprising bearings (4a and 4b) and a bearing holder (93), and wherein said impeller (5), said rotor (3) and the shaft (91) of said impeller are fixed together, said inner ring of the bearings being fixed to said shaft and the outer
30 rings of said bearings being hold by the bearing holder, which is fixed in the apparatus, and said rotor being shifted outside the stator, preferentially at an equal distance of each of the three stator sectors (8a, 8b and 8c), so that the stator also generates on the rotor an axial force oriented
35 along said shaft, thus generating a preload on the bearings.

8. The apparatus according to any one of the previous claims, further comprising a power supply manager (29)

connected to the power supply source (30 or 31), said power supply manager comprising a current sensor (55), a comparator (53), a load resistor (54) and a mean to switch on the load resistor between the positive power supply and the ground when
5 the current measured by said current sensor is negative, in order to dissipate this current in said load resistor by thermal effect.

9. The apparatus according to any of the precedent claims, being designed to be connected to a tube of a diameter
10 less than 22 millimeters, a first extremity of the tube being connected to the air outlet of the blower (33) and a second extremity of the tube being connected to a mask in which the patient breaths.

10. The apparatus according to any of the precedent
15 claims further comprising :

- at least one means (110) for detecting the patient's breathing parameters,
- a pressure control unit (37) to adjust the pressure delivered by said blower at the level of said mask, and
20 comprising an estimation module (100) connected to the means for detecting the patient's breathing parameters, in order that the estimation module is able to determine when the patient is inspiring or expiring and in response the pressure to apply to the patient's mask, during inspiration and during
25 expiration.

11. The apparatus according to claim 10, wherein said at least one means detects the patient's airflow and send it to a breath estimator (132) which determines the airflow as a function of time and transmit this function to said estimation
30 module (100) which will thus estimate the pressure to apply to patient's mask according to the airflow function, in order to decrease the effort of the patient's lung while maintaining, during one breath step, the average value of the pressure at the mask P_M equal to the pressure of treatment,
35 the estimation module (100) preferentially determining the pressure P_M at the mask as a function of time.

12. The apparatus according to claim 10 or 11, wherein the control unit comprises a non volatile memory in which the clinician can enter clinical settings (120) comprising at least the treatment pressure and possibly the pressure to
5 apply according to the patient's breathing parameters, said estimation module providing the pressure PM according to these clinical settings and to the patient's breathing parameters.

13. The apparatus according to claim 12, wherein the patient can enter patient settings (122) in said non volatile
10 memory, said estimation module (100) providing the pressure according to these patient settings and to the patient's breathing parameters within bounds given by the clinician settings (120).

14. The apparatus according to any one of claim 10 to
15 13, in which the estimation module (100) is able to determine that an event (E_1 , E_2 or E_3) occurs in patient's breathing thus enabling said pressure control unit (37) to provide the blower (33) with the tension to apply to adjust the pressure at patient's mask.

15. The apparatus according to any one of claim 10 to
20 14, wherein said means (22 and 23) for detecting the patient's breathing parameters enable the pressure control unit (2) to compute the airflow at patient's mask, said estimation module (100) determining that an event (E_1 , E_2 or E_3) is occurring
25 with the airflow parameters or shape.

16. The apparatus according to claim 10 to 15, wherein said estimation module (100) has an inspiration output (102) where said estimation module set the mask pressure PM value during inspiration, and wherein said estimation module has an
30 expiration out put (104) where said estimation module set the mask pressure PM value during expiration, said pressure control unit (37) comprising a switch (108) which is connected alternatively to the inspiration output or expiration output according to patient's breathing.

35 17. The apparatus according to claim 10 to 16, wherein the means for detecting the patient's breathing parameters comprise a pressure sensor (23) for sensing the pressure at

said first tube extremity and one pressure sensor (22) for sensing the pressure at the extremity of the tube connected to the blower outlet, said airflow computation module being able to calculate the airflow from these pressures and from the tube airflow resistance coefficient KT.

18. The apparatus according to claim 10 to 17, wherein the apparatus further comprises a starting mean which, when actuated, orders the estimation module (100) to detect a breathing activity, said estimator module sending the instruction to stop the blower (33) if no activity is sensed after a given delay.

19. The apparatus according to any one of the previous claims, wherein a power supply manager (29) comprise a communication module (65) which transmits the data through the power source wires.

20. The apparatus according to any one of the previous claims, said communication module (65) comprises a Frequency Shift Keying (FSK) modulator (50) which transforms the binary data sent by the apparatus sensors or elements in a modulation of the frequency of the tension applied on a voltage controlled current source (52), connected to the external power supply, so that the voltage controlled current source transmits the modulation corresponding to the data, a FSK demodulator converting the voltage frequency modulation into binary data (61) and transmits it to the elements, so that each sensor or module connected to the power source is able to receive or transmit information.

21. The apparatus according to any of the previous claims, further comprising a phonic insulation box (34) wherein the blower (33) is placed, said impeller (5) having a size less than 60 mm and comprising between 15 and 45 blades, preferentially 27, so that the impeller rotates at a speed that generates a sound at a high frequency, enabling said box to insulate the patient from this noise.

22. The apparatus according any one of the previous claims, said apparatus being used for the treatment of breathing anomalies, such as snoring, apneas, or hypopneas.

23. The apparatus according to claim 5 to 22, wherein said stator (8) is obtained by a strip wound cores technique with a high grade thin silicon steel, of about 0.05 mm thickness.